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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/654,987	09/05/2000	Aiden Flanagan	S63.2-8765	7494

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6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

YAO, SAM CHAUN CUA

ART UNIT	PAPER NUMBER
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1733

10

DATE MAILED: 05/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/654,987

Applicant(s)

FLANAGAN, AIDEN

Examiner

Sam Chuan C. Yao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 2-13, 16-23, 25, 26 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 14, 15, 24 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 and 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that *"Claim 18 is directed to a process for forming a fluid tight seal between a polymeric body and a polymeric dilation member surrounding the polymeric body, where the polymeric body is a catheter tube."*; and similarly argued for claim 19. This is not found persuasive because these claims are dependent on independent claim 17 where the patentability of claim 17 is divergent from the claims of group I (see Paper No. 5 for details).

As for Applicant's request for reconsideration to claim 26 upon determination of the allowability of group I, as noted in the written restriction, **all non-elected methods claims will be rejoined, depending on the basis of allowable subject matter in the claims.**

The requirement is still deemed proper and is therefore made FINAL.

In a subsequent telephone interview, Examiner noted the concern raised by Mr. Grad in a written supplemental response in Paper No. 8. Examiner informed Mr. Grad that, he is given an opportunity to elect between a balloon species, and species M & N. Mr. Grad indicated that Applicant is maintaining the elected species set forth in Paper No. 8. According to Mr Grad, claims 1, 14-15, 24 and 27-29 are readable to the elected group and species.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 15, 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Forman (US 5,501,759).

It is taken that, the limitation of “generating at least one annular beam of electromagnetic energy ...” reads on an embodiment taught by Forman where fixture (118) is provided with 6 radial openings for 6 optical fibers (122-132); wherein, these optical fibers are connected to a laser energy source (134) and are used to uniformly distribute a laser energy beam around a “*bond area and slightly overlapping one another along the annular bond site to insure substantially even energy distribution.*” (emphasis added). Also see column 1 lines 11-16; column 5 lines 24-35; column 6 lines 31-61; column 7 lines 42-54; and figures 8-14.

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It is further taken that, since the cross-sectional area of optical fibers is substantially circular, the laser beam exiting from the optical fibers is inherently substantially circular.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 15, and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forman (US 5,501,759) in view of Wysocki et al (US 5,339,380).

Note: claims 1, 15, and 27-29 are taken to be anticipated by Forman. This paragraph is used as an alternative rejection, in case, the limitation “*generating at least one annular beam of electromagnetic energy*” defines over the teachings of Forman where laser is distributed around a catheter tube via optical fibers to form an “*annular bond site*”.

Forman, drawn to laser welding a balloon catheter onto a catheter tube, substantially discloses the recited process of claim 1 (col.1 lines 11-16; col. 5 lines 24-35; col. 6 lines 31-61; col. 7 lines 42-54; and figures 8-14. Forman appears to be different from the recited claims, in that, Forman does not explicitly teach “*generating at least one annular beam of electromagnetic energy*” to bond a balloon onto a catheter. However, it would have been obvious in the art to

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“generat[e] at least one annular beam of electromagnetic energy” in bonding a balloon onto a catheter in the process taught by Forman because: Wysocki et al teaches using a laser and a parabolic mirror to *“generat[e] at least one annular beam of electromagnetic energy”* to fusion-weld a pair of optical fibers, and further discloses that, the optical fibers are uniformly heated around their circumference and the process produces *“highly reproducible results ...”* (col. 2 lines 18-68). The collective teachings of Forman and Wysocki et al would have suggested to one in the art to incorporate the laser heating technique of Wysocki et al to the process of Forman in welding a balloon catheter to a catheter tube because it provides an effective and yet highly reproducible way of uniformly heating around a catheter tube and catheter balloon so that they can be uniformly welded together and form a uniform “fluid tight seals” (col. 1 lines 14-16).

It is taken that, the laser beam in the process of either Forman or Wysocki et al is substantially circular. In any event, such would have been obvious in the art as such is conventional in the art.

8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references set forth in numbered paragraph 5 or 7 as applied to claim 1 above, and further in view of Erlich (US 4,772,275) or Vrba (US 5,957,930).

Erlich teaches adhesively bonding or welding a catheter sheath (22) onto a catheter tube (12) to attach them together (col. 4 lines 51-64).

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Vrba teaches adhesively bonding a retractable sheath (106) onto a catheter tube (120) (col. 6 lines 44-50; figure 14)

It would have been obvious in the art to apply the laser heat-welding technique of Forman or (Forman taken with Wysocki) in attaching a catheter sheath onto a catheter tube in the process taught by Erlich or Vrba because: Forman or (Forman taken with Wysocki) teaches an effective way to uniformly and locally heat-weld a polymeric material concentrically disposed around a circumference of a catheter tube using a laser; and, because Forman teaches the disadvantages of using an adhesive and the advantages of forming a fusion bond in the process of making a catheter tube (col. 2 lines 24-28).

9. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Forman (US 5,501,759) as applied to claim 1 or 27 in numbered paragraph 5 above.

Forman further teaches that, after performing a distal bonding, a proximal bonding is also performed in "substantially the same process" (col. 9 lines 13-18). It would have been obvious in the art to modify the process of Forman and simultaneously heat-weld a balloon and a catheter tube around distal and proximal portions in order to increase the production efficiency. All that would be needed is to provide another set of 6 optical fibers, a fixture, and if needed another laser source.

10. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references set forth in numbered paragraph 7 as applied to claim 1 or 27 above, and further in view of Buchroeder et al (US 4,623,776).

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Forman further teaches that, after performing a distal bonding, a proximal bonding is also performed in "substantially the same process" (col. 9 lines 13-18). It would have been obvious in the art, motivated by the desire to increase production efficiency, to simultaneously heat-weld a balloon and a catheter tube around distal and proximal portions because it is old in the art to simultaneously laser heat a tubular work-piece at two different locations from a ring of laser light by setting an optical system to a proper angular arrangement as exemplified in the teachings of Buchroeder et al (figure 3); and because one in the art would have reasonably been able to construct an optical arrangement such that, a parabolic mirror similar to the one taught by Wysocki et al can be used to simultaneously focus beams of laser light at the two bonding portions of the catheter tube and balloon using two of laser energy sources and two focusing lenses.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sam Chuan C. Yao whose telephone number is (703) 308-4788. The examiner can normally be reached on Monday-Friday with second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael W Ball can be reached on (703) 308-2058. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703) 305-7115 for regular communications and (703) 305-7718 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0651.



Sam Chuan C. Yao
Primary Examiner
Art Unit 1733

scy
May 20, 2002